Instruction manual

bon E-20 SE

GA bon E-20 SE Rev 1.1 E 260406

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Appendix: EC Declaration of conformity

1 Introduction

Dear customer

Thank you for purchasing our refraction unit bon E-20 SE. Please read the operating instructions carefully before using the system. Keep these instruction manual safe for future use. **Please observe the safety instructions.**
If you have any further questions, please contact our customer helpline.

Meaning of the symbols in the operating instructions

Caution! Please observe safety instructions with this symbol to prevent personal danger or damage to property.

Important! Indicates particularly important information to maintain the function of the device/system or to extend its life.

Note! Indicates information for correct use so that errors may be avoided.

This publication may not be copied or transferred without prior agreement from bon Optic.
bon Optic reserves the right to make changes in the interest of technical development. These operating instructions are not subject to updating.

2 Important information

Manufacturer: bon Optic Vertriebsgesellschaft mbH · Stellmacherstr. 14 · D- 23556 Lübeck

2.1 Information about the device

Device description: bon E-20 SE

2.2 Intended purpose and classification

The bon E-20 SE refraction unit is used in conjunction with ophthalmological instruments such as slitlamps and opthalmometers. During use in an ophthalmic examination these devices are positioned in front of the patient.
According to the classification rules of the Medical Device Directive 93/42/EWG, the bon E-20 SE refraction unit is classified as a non invasive medical active product class 1.

2.3 Liability

The Refraction Unit is manufactured according to the recognized technical safety regulations and is tested to the strictest quality measures. The company bon Optic accepts responsibility for the safety, reliability and performance of the device only when:

- Mounting, modification and commissioning are carried out by a person(s) authorised to do so by bon Optic.
- The power supply to which the device is connected corresponds to the national legislation.
- The device is only used in accordance with this instruction manual.
- The user operates in accordance with the Medical Device Use Practice (MPBetreibV).

The manufacturer will not accept liability should the system be assembled, amended or commissioned by an unauthorised person, should it be improperly serviced, or should it be other than as described under 2.2 .

2.4 Scope of delivery

1 Piece Refraction Unit E-20 SE
(Your Refraction Unit may differ from that illustrated in 2.1 depending on the Configuration purchased.)

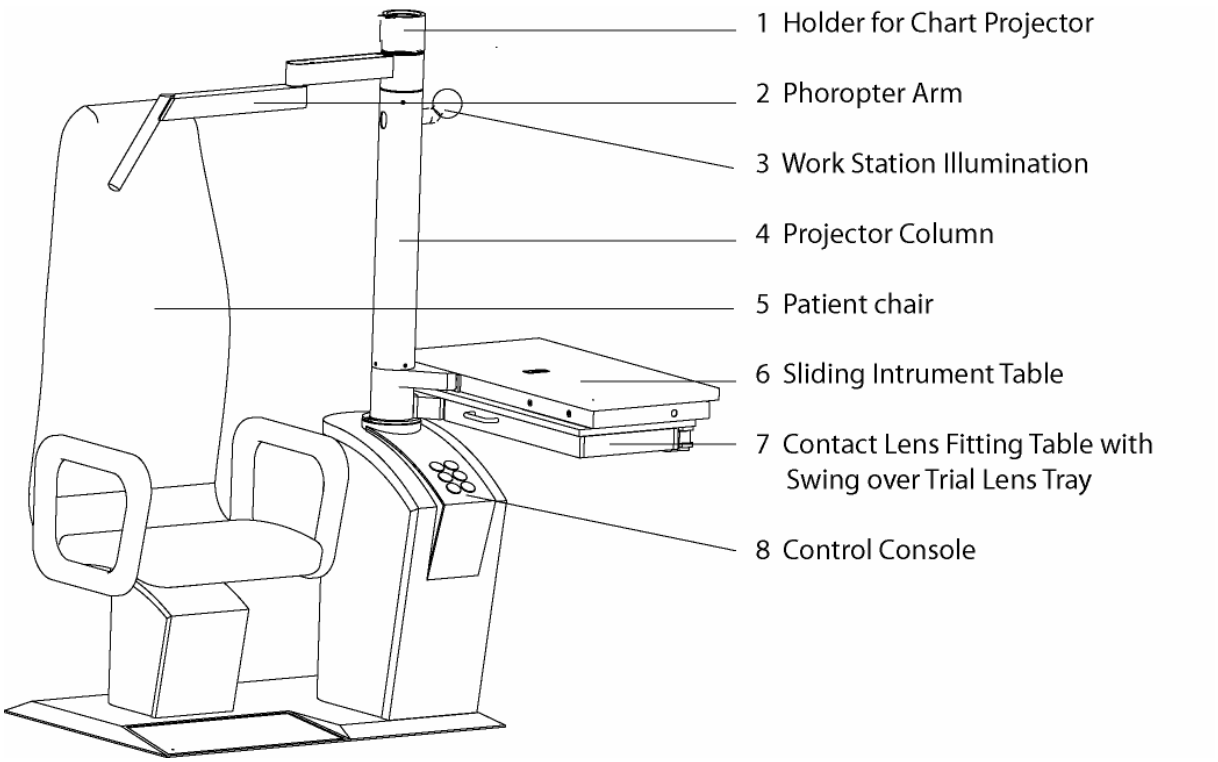

1 Holder for Chart Projector
2 Phoropter Arm
3 Work Station Illumination
4 Projector Column
5 Patient chair
6 Sliding Intrument Table
7 Contact Lens Fitting Table with Swing over Trial Lens Tray
8 Control Console

Fig. 2-1: bon E-20 SE with maximum parts and accessories

2 Pieces of Table connections for the table top devices (only supplied when a table is supplied).

1 Mains cable 1,5 m

1 Instruction manual

1 Set of fuses consisting of:

2 pieces T 3,15 A (for fuse F1, F4)
2 pieces T 5,0 A (for fuse F5, F6)
1 piece T 4,0 A (for fuse F2)
1 piece T 6,3 A (for fuse F3)

3 Safety instructions

Please adhere to the legal guidelines for accident preventions and take note of the following safety instructions.

Set up and Installation:

- The Refraction Unit must not be installed or used in damp rooms.
- Please ensure the refraction unit is mounted on a level and stable surface.
- The power must correlate to that shown on the Type label.
- The maximum carrying capacity of the translation table (6) is 40 kg, 25 kg maximum can be placed in position 1 of the translation table.

To Operate:

- Do not expose the system to any temperature extremes. The recommended usage temperature lies between + 10° and + 40° C.
- Avoid dripping water and water spray.
- The maximum carrying capacity of the patient chair (5) is 170 kg. This must not be exceeded.
- When the translation table (6) and the contact lens fitting table (7) are swung into position. There is a scissor movement. This presents a risk of trapping!
- The elevation column of the patient chair is not designed for continuous use. After continuous use for 60 seconds a cooling off period of 9 minutes must be adhered to.
- Please note that neither the translation table (6) nor the contact lens fitting (7) should be allowed to hit the patient` legs.
- Do not exert any unnecessary pressure on the contact lens table (e.g. Leaning with the hand).
- Ensure that the phoropter arm (2) does not hit the patient (e.g. as the chair moves upwards).
- Longer use of the examination lamp (3) can lead to a heating of the lamp housing. There is a danger of burning.

Other:

- Do not pull the cable when removing the plug from the socket.
- Position the cable so that there is no risk of walking on it or falling over it. Any other risk of damage to the cable must be avoided (e.g. sharp edges or strong heat).
- The plug must be removed from the socket before carrying out repairs, maintenance or commissioning.

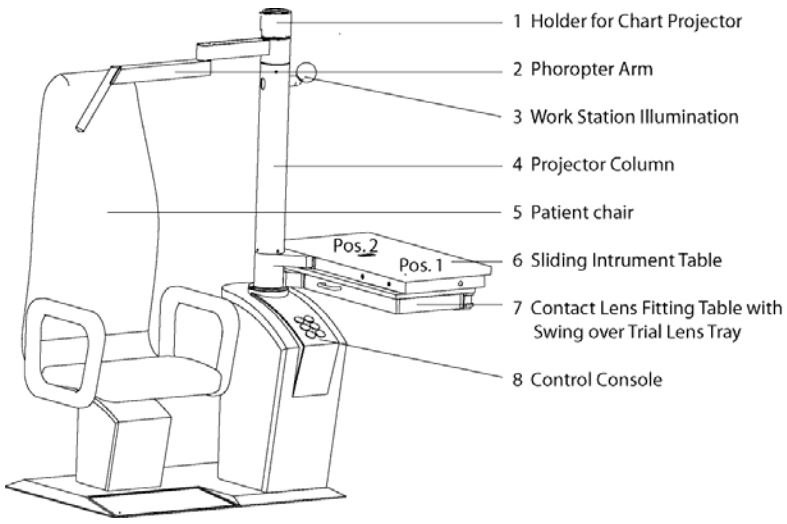

1 Holder for Chart Projector
2 Phoropter Arm
3 Work Station Illumination
4 Projector Column
5 Patient chair
Pos. 2
Pos. 1
6 Sliding Intrument Table
7 Contact Lens Fitting Table with Swing over Trial Lens Tray
8 Control Console

Fig. 3-1: Refraction Unit bon E-20 SE

4 Set up, installation and reconditioning

The set up and installation of the refraction unit must be carried out by qualified bon Optic personnel.

Modification or reconditioning of the refraction unit must only be carried out by bon Optic authorized personnel. Medical devices which are to be connected to the electrical supply of the refraction unit must be proved to fulfill their DIN - EN as well as IEC specifications. All configurations must fulfill the requirements of the system norms DIN EN 60601-1-1 (IEC 601-1). Connection of non medical devices must not detract from the safety of the system. Modifications to the refraction unit must not endanger patients, users or the surrounding area.

Repairs that can be carried out by the user can be found in chapter 6: Care and Maintenance.

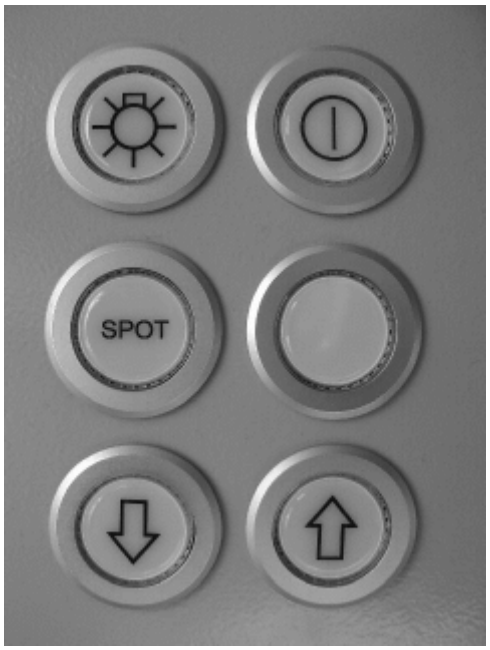
5 Operation

5.1 Layout of the switches und buttons on the control console

Switch for dimming the room lights. (Supplied on customer request.)

On/Off switch of the examination light on the projector column.

Switch to activate the height adjustment of the patient chair (down).



On/Off switch (function switch) of the refraction unit.

This switch is not occupied as standard. It can be activate on request to meet customer needs.

Switch for adjustment of the patient chair (up).

Fig. 5-1: Switches on the control console

5.2 Commissioning

1) Please ensure that the refraction unit is connected to the power supply with the intended power cable.
2) Press the On/Off switch on the control console (8).
3) The refraction unit is ready for use when the switches as well as the buttons on the control console are illuminated.

5.3 Description and function of the components

Please ensure that the refraction unit is connected to the power supply with the intended power cable.

5.3.1 Translation table

The translation table serves to carry ophthalmic instruments such as slit lamps and ophthalmometers. These instruments can be moved using the table into position 1 and position 2.

Power Supply for the table top devices

Power is supplied to the table top devices via the connection ports in the translation table. To configure / change the power supply please contact the bon Optic qualified personnel.
More detailed information on power supply can be found in chapter 8: Technical Data.

Power will be supplied automatically to the table top device on switching into working position 1 or 2. The translation table ensures a via a potentiometer the smooth introduction of power (for e.g. the brightness adjustment on the slit lamp).

Operation

1) Swing the translation table into the required position.
2) Lock the table in position.
3) Slide the table into the required working position 1 or 2.
4) In order to swing back out of the way unlock the table.

When the refraction unit is switched off the table lock retains it's status from prior to switch off. That means that after switching on the refraction unit again, the table lock is activated if the table lock was in the on position when the refraction unit was last switched off.

Fig. 5-2: Switch for locking the table

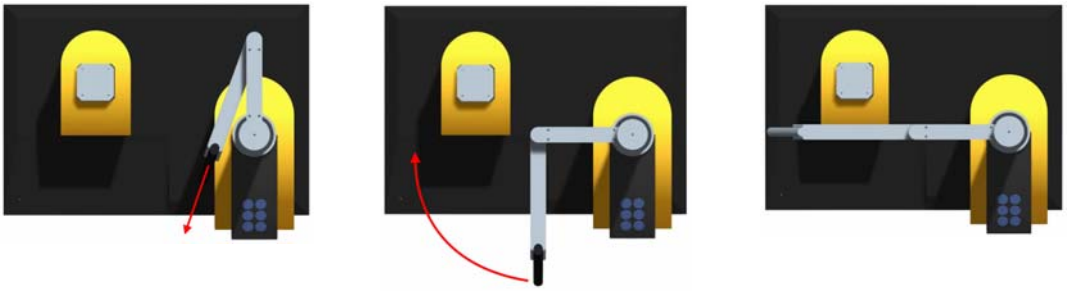
Try not to be forceful when activating/deactivating the table lock!

5.3.2 Patient chair

The height adjustment (Up and down movement) of the patient chair is activated via a switch on the control console. (see illustration. 5.1). When the contact lens table is swung out of the rest position the chair movement will be automatically deactivated. Thus preventing the patient from colliding with the table and any resulting damage to the refraction unit.

5.3.3 Phoropter arm

In order to move the phoropter from the rest position, as the user pull the phoropter arm back on itself (shown in illustration 5-3, Pos.1). Turn the lower part of the arm towards the patient (illustration 5-3, Pos. 2).
Operate in reverse in order to move the phoropter back into the rest position.



Position 1: Rest position | Position 2: Phoropter arm angled | Position 3: Phoropter arm in extamination position

Fig. 5-3: Phoropter Arm (Positions)

The phoropter arm serves exclusively as the carrier for the phoropter. Do not any hang other objects on the phoropter arm.

The power connection for a chart projector on the projector column has a maximum capacity of 200 VA.

5.3.4 Contact lens fitting table with trial lens tray

The contact lens fitting table with the trial lens tray form a single unit and can be swung into the required position in the same way as the translation table. (see chapter 5.3.1) These elements will however not be influenced by the table lock.

The trial lens tray can be swung into position under the contact lens table using the handle.

Do not place any objects on the contact lens table that could scratch the mirror.

6 Care and maintenance

6.1 Care

Clean the refraction unit with a clean and damp chamois leather. Do not use any abrasive or aggressive cleaning fluids!

6.2 Maintenance

The refraction unit if used appropriately does not require any regular maintenance.
For repairs or in the event of technical problems please contact the customer care team at bon Optic.

6.3 Repairs that can be carried out by the user

The following repairs can be carried out by the user.

6.3.1 Changing the bulb in the examination lamp

Bulb used: Halogen mirror lamp with reflector and safety glass
(12 V / 20 W), Socket GU 5.3

1) Before commencing the repair work remove the plug from the mains socket.
2) In order to avoid burns allow the lamp to cool down before changing it.
3) Remove the lamp by hand out of it´s holder.
4) Place the new lamp in the holder. Please ensure that the contact pins are not bent during this process. The position of the contact pins is not relevant.

6.3.2 Safety fuse

Only use fuses with the safety values listed in illustration 6-1 Type (T)!

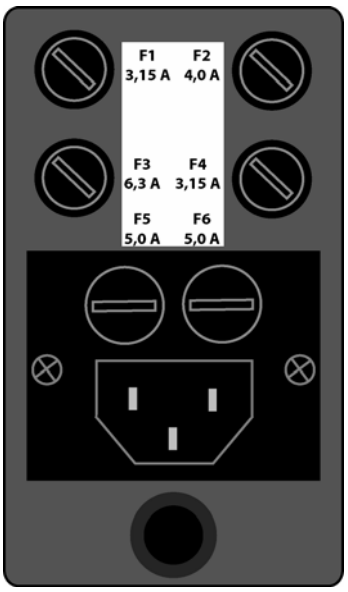


Fig. 6-1: Fuses behind the refraction unit

1) Bevore changing the fuse removes the plug from the mains socket.
2) Open the relevant fuse holder with a screw driver.
3) Remove the old fuse from the holder and place a new fuse of the same type in the holder.
4) Push the fuse holder back into the fuse port.
5) Close the fuse holder with a screw driver.

6.3.3 Function defects

Component	Defect	Fuse	Fuse Value
Chair elevation	Up and down movement of patient chair does not function	**F1**	T 3,15 A
Translation table (Examination instruments)	The table cannot be locked, the instruments do not work. **Relay „clicks“ upon activating the table lock switch**	**F2**	T 4,0 A
Translation table (Examination instruments)	The table cannot be locked into position instruments do not work. **Relay „clicks“ without table lock being activated**	**F3**	T 6,3 A
Examination Light	Examination light and key pad illumination do not function	**F4**	T 3,15 A
Main fuse power supply	Refraction unit does not function	**F5**	T 5,0 A
Main fuse power supply	Refraction unit does not function	**F6**	T 5,0 A

Table 1: Defects

7 Warranty

Any defects due to material or manufacturing errors which occur within 24 Months following purchase will be verified free of charge. The unit will be replaced free of charge at our discretion should we deem it necessary.

The following conditions apply in both instances:

- The invoice with the purchase date applies.
- The device was used according to the instructions and for the specified purpose.
- Any repairs were carried out by bon personnel or persons authorised to do so by bon Optic.

Repairs under warranty do not trigger an extension of the existing warranty nor do they initiate a new warranty period. The bon warranty does not apply to consumable products.

Furthermore the terms and conditions of the company bon Optic apply.

8 Technical data

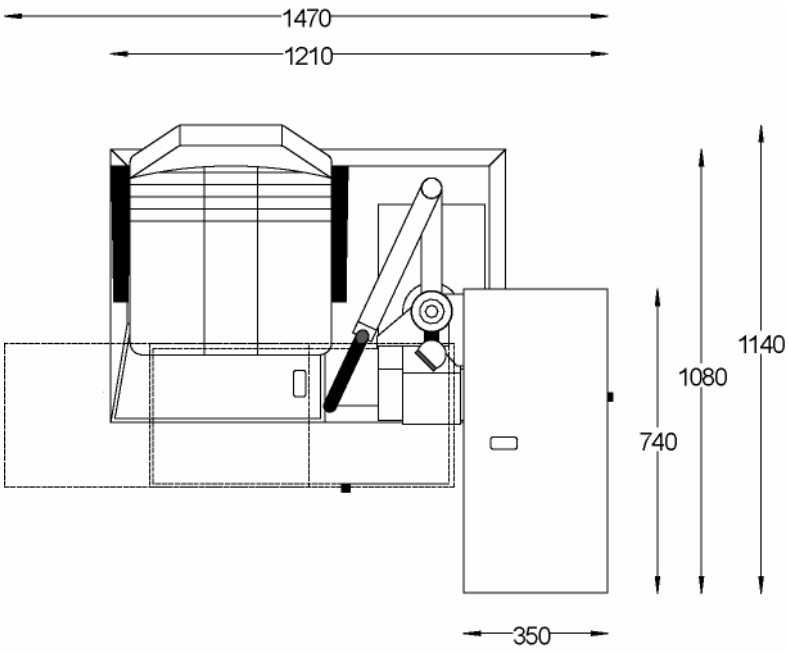


Fig. 8-1: Refraction unit bon E-20 SE (View from above)

Other Dimensions	
Width (Base plate)	96 cm
Depth (Base plate)	66 cm
Height (without projector), standard components	165 cm
Height (Translation table)	85 cm
Seat Height (At lowest point)	41,5 cm
Seat Height (At highest point)	63 cm

Weight	
Maximal configuration without instruments	ca. 120 kg

Electrical Data Refraction Unit	
Current	230 V AC
Frequency	50 / 60 Hz
Input Power	750 VA
Output 1 Translation table	6 V AC / 12 V AC
Output 2 Translation table	6 V AC / 12 V AC
Examination light	12 V AC / 20 W
Protection class	I
Device type	B
Protection type	IP 21

Maximum Output Power: Output 1 + Output 2 = 88 W

Conditions of Use Refraction Unit	
Ambient temperature	+10° C to +40° C
Relative air humidity	30% to 75%
Air pressure	700 hPa to 1060 hPa

Chair Elevation	
Current supply	230 V / 50 Hz
Power intake	2,2 A
Protection class	I
Max. axial strain	1800 N (ca. 170 kg)
ED (Switch in duration chair column)	S2 10% Basic 10 min.
Elevation	215 mm
Speed under strain	ca. 16 mm/s
Thermoswitch	Yes
End switch up/down	Yes

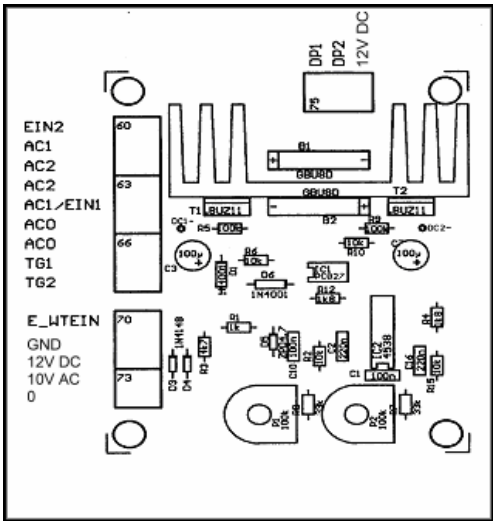


Fig. 8-2: Circuit board (power supply)

Feeder clamp	Name	Description
60	EIN2	Connection for jumper
61	AC1	Connection for jumper
62	AC2	Connection for jumper
63	AC2	Voltage for control: 14 V AC
64	AC1/EIN1	Voltage for control: 8,3 V AC
65	AC0	Output voltage for tabletop unit: Ground
66	AC0	Output voltage for tabletop unit: Ground
67	TG1	Output voltage for tabletop unit 1 (6 V AV / 12 V AC)
68	TG2	Output voltage for tabletop unit 2 (6 V AV / 12 V AC)
70	E_WTEIN	Switching voltage: 12 V AC
71	GND	Switching voltage: Ground
72	12 V DC	Switching voltage: 12 V DC
73	10VAC(SB)	Operating voltage: 10 V AC
74	-	Operating voltage: Ground
75	DP1	Potentiometer adjustable table
76	DP2	Potentiometer adjustable table
77	12V DC	Voltage 12 V DC

Table 2: Feeder clamp (power supply)

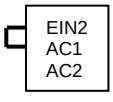
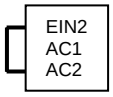
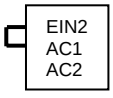
Jumper on Feeder clamp	Input voltage	Output	
		Connection Tabletop unit 1 (TG1)	Connection Tabletop unit 2 (TG2)
		6 V	6 V
	Change voltage: Feeder clamp 63 and 64	12 V	6 V
	Change voltage: Feeder clamp 63 and 64	12 V	12 V

Table 3: Circuit (power supply)

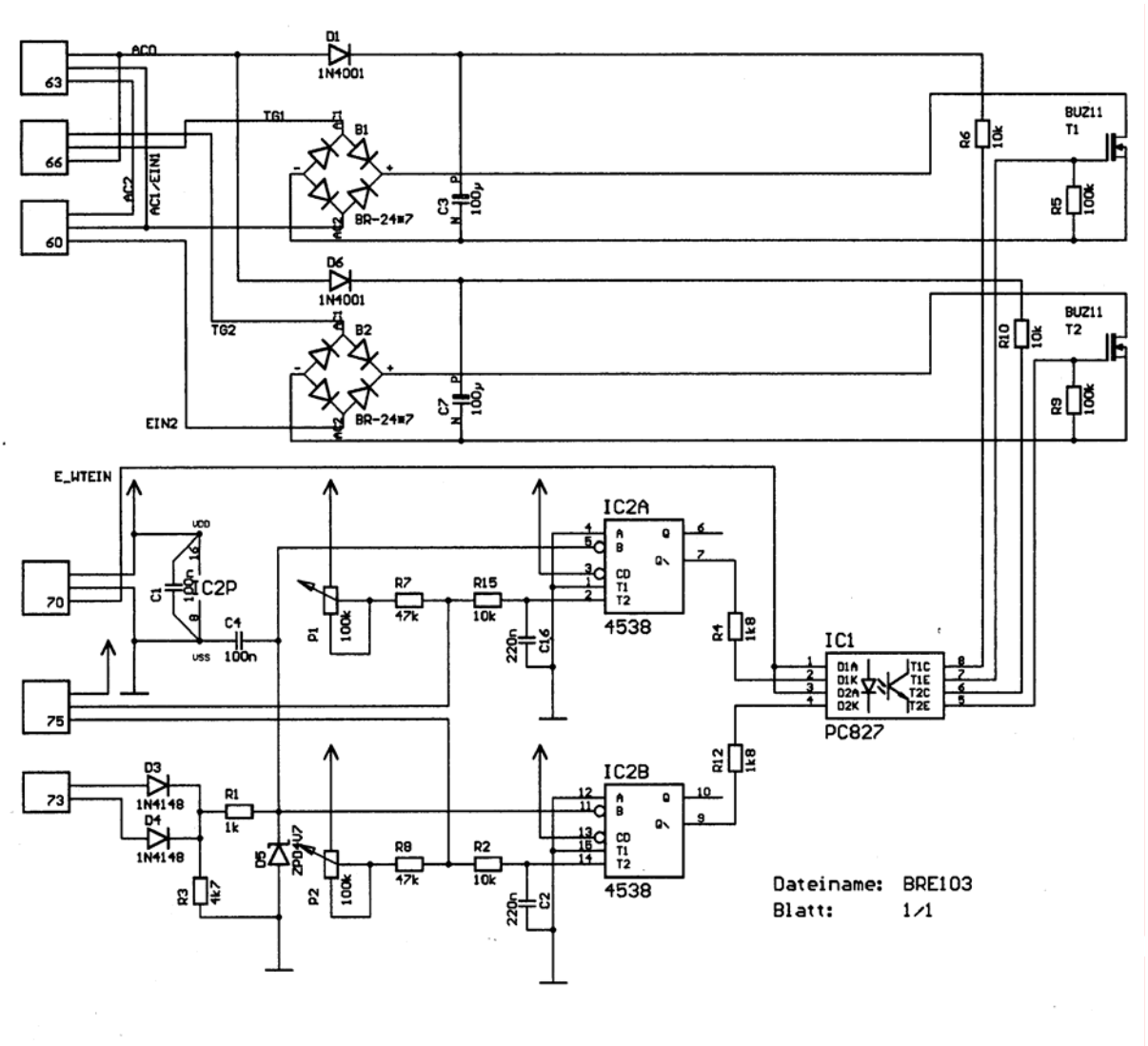


Fig. 8-3: Circuit diagram

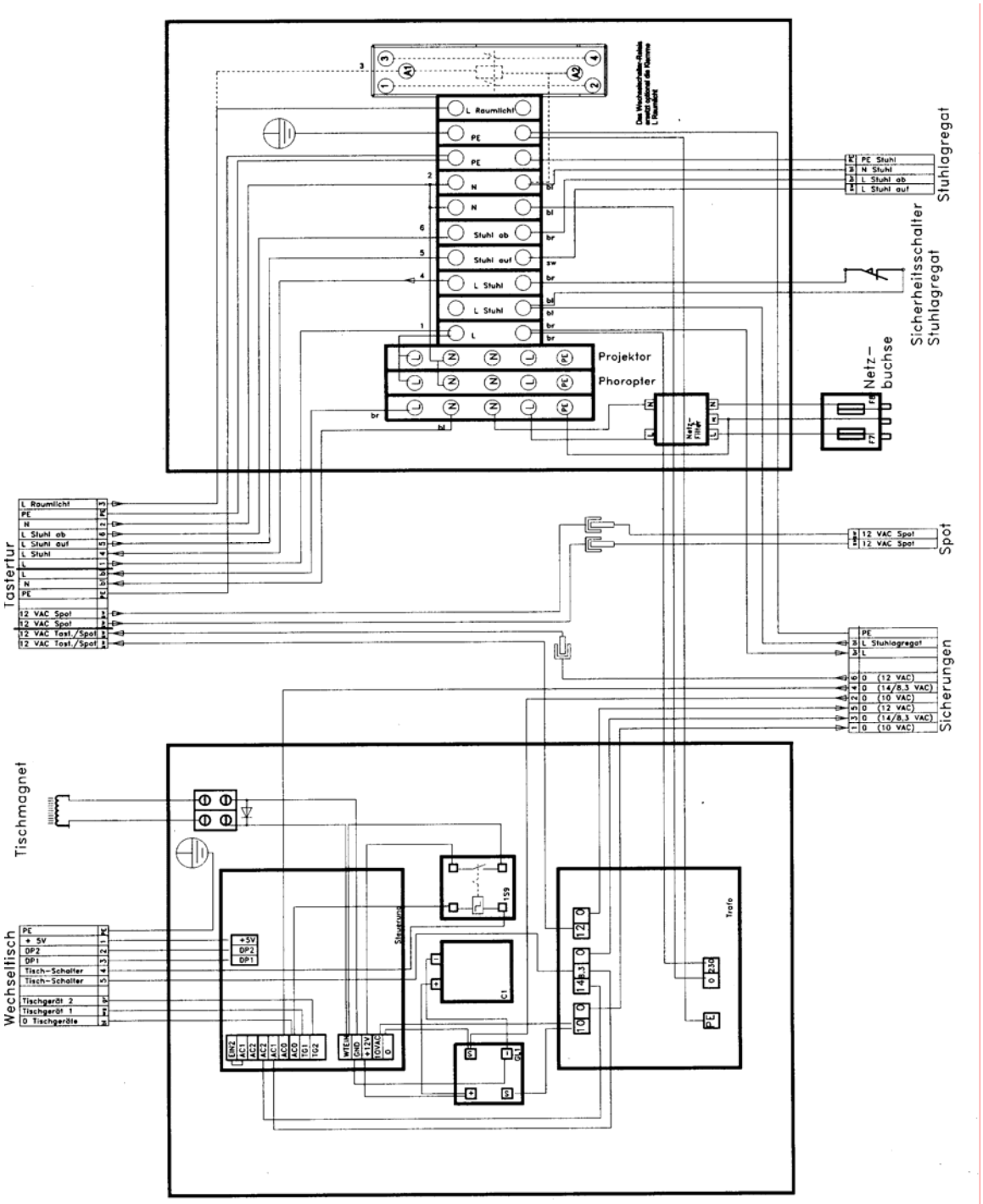


Fig. 8-4: Connecting diagram refraction unit bon E-20 SE

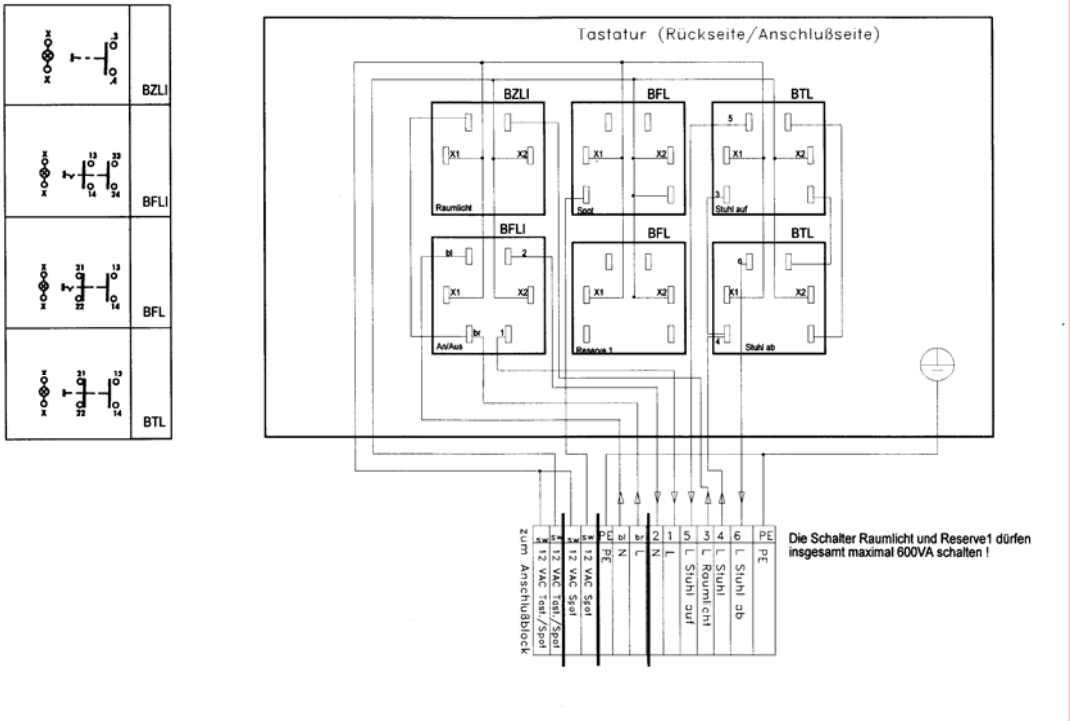


Fig. 8-5: Connecting diagram control console

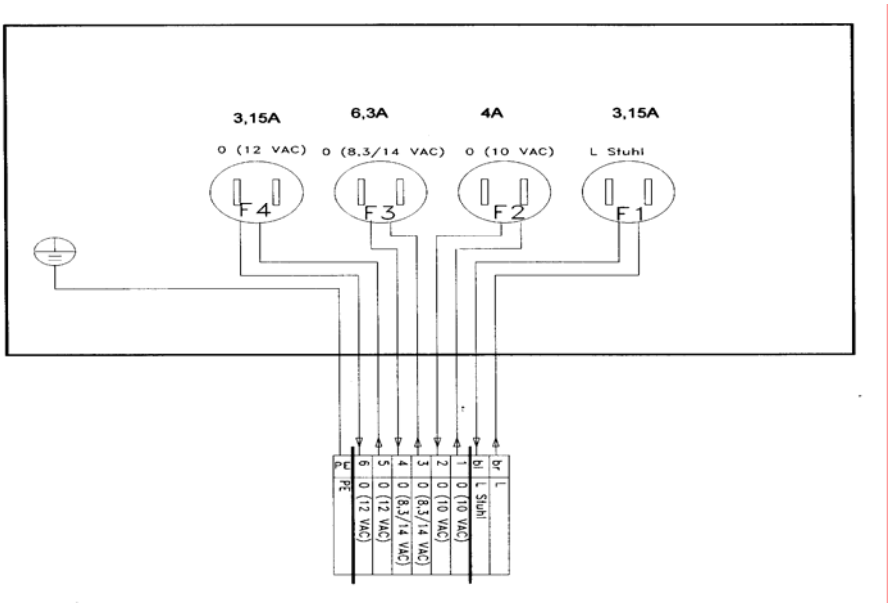


Fig. 8-6: Connecting diagram fuse (back control console)

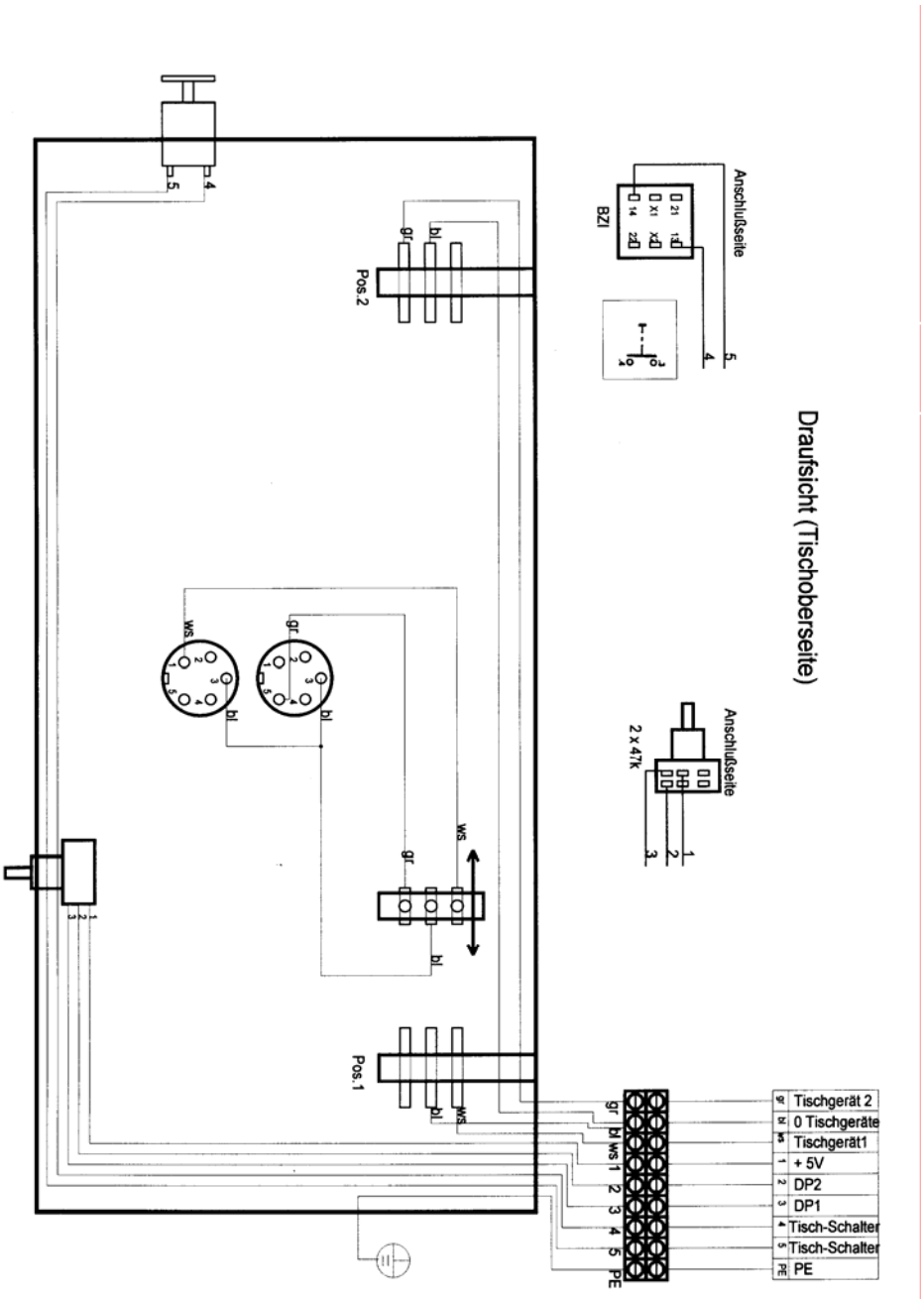


Fig. 8-7: Connecting diagram adjustable table

9 Other information

Disposal of old Electrical & Electronic Equipment (Applicable throughout the European Union and other European countries with separate collection programs)

This symbol, found on your product or on its packaging, indicates that this product should not be treated as household waste when you wish to dispose of it. Instead, it should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. If you have any further questions, please contact bon optic.

In the case of an EMC-defect (**E**lektro-**M**agnetic **C**ompatibility) please contact the customer care team bon Optic.

Type plate	
	Fuse
	Read the instructions
	Level protection Typ B

Transport and store requirements	
	Temperature: -5 °C to +45 °C (+23 °F to +113 °F)
	Air Pressure: 650 hPa to 1100 hPa
	Relative Humidity: 25% to 80%
Maximum conditions not longer than 60 consecutive days.	

EU - KONFORMITÄTSERKLÄRUNG
EC – DECLARATION OF CONFORMITY

Hersteller-Adresse: (Manufacturer adress)	bon Optic Vertriebsgesellschaft mbH Stellmacherstraße 14 D-23556 Lübeck
Gerätetyp / UMDNS-CODE: (Device typ/ UMDNS-CODE)	Untersuchungs-/Behandlungsplatz (18-014)
Gerätebezeichnung: (Device name)	**Refraktionseinheit bon E-20/E-20 SE** **Refraction unit bon E-20/E-20 SE**
Klassifizierung: (Classification)	**1** (Richtlinie 93/42/EWG, Anhang IX, Regel 1) **1** (MDD 93/42/EEC, annex IX, rule 1)

Wir erklären hiermit die Übereinstimmung des vorgenannten Produkts mit der EU-Richtlinie 93/42/EWG über Medizinprodukte.

We declare the compliance of the device with the requirements of the Derective 93/42/EEC about medical devices.

Angewandete Normen: (Applicable standards)	DIN EN 60601-1 DIN EN 60601-1-2 EN 1441	(03/96) (09/94) (10/97)
Überwachungsbehörde/ ID-Nr.: (Notified body/ Identification number)	**TÜV Berlin / 0197**	

Das Gerät ist gekennzeichnet mit / The device is marked with CE

Lübeck, 01 June 2004

(H. Jochen Kaber, managing director)